



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,739	09/19/2005	Richard Jiao	21273P	4782
210	7590	09/25/2008	EXAMINER	
MERCK AND CO., INC			CHANG, CELIA C	
P O BOX 2000				
RAHWAY, NJ 07065-0907			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			09/25/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/549,739	JIAO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 June 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.  
 4a) Of the above claim(s) 2,4,5,7,15-19,21 and 22 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 23 is/are rejected.  
 7) Claim(s) 1,3,6,8-14 and 20 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>08/04/08</u> .	6) <input type="checkbox"/> Other: _____ .

### **DETAILED ACTION**

1. Applicant's election without traverse of group II, claims 6, 8, 9-14 and claims 1, 3, 20 reading on formula II, X is C, R<sup>7</sup> and R<sup>8</sup> forms spiro-indanyl/indenyl ring, R<sup>2</sup> and R<sup>19</sup> are independent substituents in the reply filed on Jun. 18, 2008 is acknowledged. Applicants' request to include R<sup>2</sup> and R<sup>9</sup> forms ring cannot be granted because R<sup>2</sup> and R<sup>9</sup> do not form rings. Further, claims 6, 8, 9-14 do not read on R<sup>2</sup> and R<sup>19</sup> forms rings. In addition, the ring system formed by R<sup>2</sup> and R<sup>19</sup> is of such diversity classified from class 540, 544 to 546 which are tremendous burden to search all the compounds. In addition, the references recited on 1449 clearly indicated that the R<sup>2</sup> and R<sup>19</sup> are independent substituents or ring structure supports separate patents see WO 02/13824 and WO 04/110376.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6, 8, 9-14, and claims 1, 3, 20 reading on formula II, X is C, R<sup>7</sup> and R<sup>8</sup> forms spiro-indanyl/indenyl ring, R<sup>2</sup> and R<sup>19</sup> are independent substituents are prosecuted. Claims 2, 4-5, 7, 15-19 and 21-23 and the remaining subject matter of claims 1, 3, 20 are withdrawn from consideration.

2. Claims 21-22 cannot be rejoined with the elected invention because the state of the chemokine receptor modulating art clearly documented that based on the structure-activity relationship, it was suggested that the small molecule CCR2 antagonists are extremely selective against the specific receptor therefore CCR2 antagonists are ineffective in treating all chemokine receptor involved physiology (see Cohen et al. whole article or Yang et al. whole article). CCR2 receptor antagonists further have been known to be useful in treating rheumatoid arthritis. Therefore, the only rejoivable claim is claim 23 when the 112 issues are removed.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is the scope of claim 23. Please note that a disease such as rheumatoid arthritis is treatable when symptom or pathology of the disease is corrected to normal physiology. It is not understood what constitutes ameliorating, controlling or reducing the risk of rheumatoid arthritis. Please note that ordinarily treating a disease and reducing risk of a

disease are completely independent and unrelated conditions. For example treating heart disease is using drug to relieve the damage of the heart etc. While treating the "risk" of heart disease can be smoking, life style, eating habits etc. Therefore, a drug effective in treating disease does not necessarily treating the "risk" of the disease. No nexus in the record was found between CCR2 receptor antagonistic compound being able to ameliorating, controlling or reducing the risk of rheumatoid arthritis.

**3.** Claims 6, 8, 9-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The structurally close compound is found in WO 01/22919 (see p.89-90) which differed form the elected compound in that the right terminal ring is substituted oxopyrimidinyl and the compounds are alpha 1a adrenergic receptor antagonists.

Claims 1, 3, 20 being drawn explicitly reading on claims 6, 8, 9-14 are objected to but can be allowable with the elected compounds when the claims are limited to the limitation of claims 6, 8, 9-14 and free of 112 issued.

**4.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
Sept. 22, 2008

*/Celia Chang/  
Primary Examiner  
Art Unit 1625*